UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

MIGHTY OAK MEDICAL, INC., Plaintiff, v. MEDACTA INTERNATIONAL SA AND MEDACTA USA, INC., Defendants.	Civil Action No. 1:22-cv-01625-GBW **JURY TRIAL DEMANDED**

PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS COUNT III OF PLAINTIFF'S COMPLAINT (D.I. 1) FOR FAILURE TO STATE A CLAIM

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I. INTRODUCTION

This patent litigation matter between two competitors specializing in patient-specific surgical solutions is over a decade in the making. Yet despite knowledge of Plaintiff Mighty Oak Medical, Inc.'s ("Mighty Oak") patents for over a decade, Defendants Medacta International SA and Medacta USA, Inc. (collectively, "Medacta") profess they know nothing about Mighty Oak's claims. The contents of Medacta's motion to dismiss, taken together with Medacta's separately-filed answer to the complaint, belie those allegations.

Medacta has admitted that it met with Mighty Oak in 2014 and 2015 and admits that it "is aware of [Mighty Oak's] IP with the Firefly technology." And the FIREFLY technology consists of spinal alignment technology embodied by the asserted patents. A subsequent June 2018 phone call between counsel for Medacta and Mighty Oak confirmed as much when the parties exchanged patent infringement claims and discussed settlement and licensing. And if there was any doubt that Medacta knew of Mighty Oak's patents, Medacta's filing of an ex parte reexamination proceeding before the United States Patent and Trademark Office to challenge Mighty Oak's U.S. Patent 8,758,357 confirms their knowledge. As plead, Medacta therefore knew of Mighty Oak's patents and knew how Mighty Oak viewed Medacta's products as infringing.

Yet in this motion to dismiss, Medacta seeks to rewrite the record to argue (1) that it cannot understand what Mighty Oak accuses of infringement and (2) that Mighty Oak's patent number 9,198,678 does not cover Medacta's products. The first argument is unlikely in light of the parties' dealings over the past decade and further in light of Mighty Oak's attachment of an element-by-element, limitation-specific claim chart to its complaint detailing which aspects of the Medacta products infringe Mighty Oak's patents.

If there was any doubt that Medacta is on notice of what Mighty Oak accuses of infringement, Medacta's response zeroing in on a specific aspect of the asserted claims removes that doubt. Medacta seeks to have the Court determine that a specific limitation—an arcuate bridge "selectively engaged" to patient-specific elements—is missing. But that is a determination of noninfringement. And that determination requires the Court to agree with Medacta's claim construction, which interprets specific elements of the patent to ultimately seek dismissal on noninfringement grounds. That ask is not what motions to dismiss are for. Indeed, the motion is nothing more than a concession from Medacta that it *understands* what Mighty Oak's infringement theories are, but merely disagrees with the *conclusion*. Noninfringement requires a decision on the merits, and that is not proper for a motion to dismiss when the allegations are taken as true. The Court should deny the motion.

II. SUMMARY OF THE ARGUMENT

A. Mighty Oak's complaint sufficiently alleges that each and every limitation of claim 11 of United States Patent 9,198,678 (the "'678 patent") is met by Medacta's products, including the MySpine Standard, MySpine Low Profile, MySpine MC, and MySpine S2AI, because Mighty Oak included a detailed, limitation-by-limitation claim chart with the complaint that demonstrates how each product infringes by analyzing Medacta's product literature.

B. Medacta impermissibly and improperly seeks a premature claim construction to attempt to dispose of Count III on the merits. At the motion to dismiss stage, however, courts do not engage in claim construction but instead determine whether it is plausible that a product could infringe. Because the allegedly missing limitation—a requirement that there be an "arcuate bridge" that "selectively engages" a "first and second patient-

specific element"—is plausibly present in Medacta's products, the motion should be denied.

III. STATEMENT OF FACTS

Plaintiff Mighty Oak is a medical device company founded with the aim of providing surgical solutions. (D.I. 1 ¶ 1.) Its products include a wide array of products encompassing surgical guides, instruments, and methods, including devices that assist in spinal fixation and spinal surgery. (*Id.* ¶ 2.) Its flagship product, the FIREFLY®, is a customizable product that enables surgeons to accommodate the unique features of a given patient's anatomy to ensure optimal placement and alignment of instruments utilized during spinal surgeries. (*Id.* ¶¶ 2-4.) Used during surgery, the FIREFLY® enables surgeons to perform safer and more accurate fusion surgeries upon patients. (*Id.*) Mighty Oak's FIREFLY® products are covered by patents, which form only part of its intellectual property portfolio. Some 35 United States patents cover Mighty Oak's products, of which 18 cover the FIREFLY® product. (*Id.* ¶ 2.) The FIREFLY® products have been recognized by the Colorado Advanced Industries Grant and as recipient of the Spine Technology Award in multiple years. (*Id.* ¶ 6.)

Medacta is also a medical device company operating in the spinal alignment guide space. Their MySpine product line first launched in 2014 with the approval of the Medacta MySpine Standard device, which was put into use later that year. (*Id.* ¶ 20.) Since then, Medacta has designed additional products within the MySpine line, including a "low profile" version launched in 2016 (*id.* ¶ 24), and the "MC" and "S2A1" variants, (*id.* ¶ 52.)

As competitors, Mighty Oak and Medacta are not strangers; the parties have known of each others' business in the customized spinal surgical solutions field at least as far back as 2012. Medacta's answer confirms that Medacta's patents contain citations to Mighty Oak's patents as of

2012. (D.I. 14 ¶ 19.) And Mighty Oak and Medacta previously met to discuss those patents vis-à-vis their respective businesses. In November 2014, Medacta wrote to Mighty Oak to state that "Medacta is aware of your IP" and proposed a meeting to "discuss opportunities to collaborate in bringing this technology to market." (D.I. 14 ¶ 21.) A meeting followed days later. (*Id.*) Two months later, in January 2015. Medacta again met with Mighty Oak to discuss "the Firefly IP situation." (*Id.* ¶ 22.) And following that meeting, in February 2015, Medacta sent a letter that analyzed Mighty Oak's patents, asserted "prior art" to Mighty Oak's patents, and declined to collaborate with Mighty Oak. (*Id.*)

From 2015 to 2017, Mighty Oak prosecuted additional patents before the Patent Office, each time citing Medacta's "prior art" during examination. Not once did the Examiner reject the claims; instead, Mighty Oak obtained admission of five additional United States patents (including the '678, '633, and '024 patents) over that reference. (D.I. 1 ¶ 23.) Mighty Oak made Medacta aware of those additional patents too: In October 2017, Mighty Oak informed Medacta of the additional issued patents and reiterated that Medacta's products infringe those and other Mighty Oak patents. (*Id.* ¶ 26.) Mighty Oak followed up with Medacta and stated that Mighty Oak viewed Medacta's products as infringing. (D.I. 14. ¶ 26.) That follow-up led to discussions between counsel for the parties regarding infringement, but communications never reached an agreement, license, or settlement. (*Id.* ¶ 27.)

What followed was a series of challenges by Medacta to Mighty Oak's patents worldwide. In December 2018, Medacta challenged Mighty Oak's '357 patent at the USPTO. (*Id.* ¶ 28.) But Medacta was unsuccessful, and so in 2019, when the USPTO confirmed patentability of all claims of the '357 patent, Mighty Oak sent a letter to request further settlement discussions. (D.I. 1 ¶ 28) Instead, Medacta opted to challenge certain of Mighty Oak's patents in European fora. (*Id.* ¶ 29.)

These challenges, too, were unsuccessful; in 2021, the European Patent Office rejected Medacta's oppositions. (*Id.*) Mighty Oak again immediately followed up to request further discussion and negotiation, but none followed. (*Id.*)

This lawsuit followed. Mighty Oak filed its complaint on December 22, 2022, accusing Medacta's MySpine products, such as the Standard, Low Profile, MC, and S2AI devices, of infringing Medacta's '357, '889, '678, '633, and '024 patents. (D.I. 1) Medacta answered-in-part as to all patents but the '678 patent and moved to dismiss-in-part the allegations concerning the '678 patent on April 10, 2023. (D.I. 13, 14.)

IV. LEGAL STANDARD

Federal complaints, even in patent infringement matters, only require a "plausible 'short and plain' statement of the plaintiff's claim" that demonstrates entitlement to relief. *Skinner v. Switzer*, 562 U.S. 521, 530 (2011) (quoting Fed. R. Civ. P. 8(a)(2)). To meet that standard, one need not "prove its case." *In re Bill of Lading Transmission & Processing Sys. Pat. Litig.*, 681 F.3d 1323, 1339 (Fed. Cir. 2012). Nor must one establish "that each element of an asserted claim is met." *Id.* at 1335. Instead, all one must do is put the "potential infringer . . . on notice of what activity . . . is being accused of infringement." *K-Tech Telecomms., Inc. v. Time Warner Cable, Inc.*, 714 F.3d 1277, 1284 (Fed. Cir. 2013).

If a defendant believes this standard is not met, then Federal Rule of Civil Procedure 12(b)(6) authorizes the filing of a motion to dismiss for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). If that complaint contains "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face,'" then the motion must be denied. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S.

544, 570 (2007)). All well-pleaded factual allegations will be accepted as true, and all reasonable inferences will be construed in favor of the plaintiff. *Id.*

In assessing the sufficiency of factual matter in a complaint, one does not decide the merits. *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337 (Fed. Cir. 2018). Similarly, one does not make substantive decisions on the merits in analyzing a motion to dismiss. *Id.* Thus, in deciding a motion to dismiss, a court will not engage in analysis of claim construction. *Id.*

V. ARGUMENT

A. Mighty Oak's complaint puts Medacta on notice and is therefore sufficient.

Mighty Oak's complaint goes above and beyond the threshold of notice pleading, providing detailed claim charts identifying how Medacta's products infringe each of Mighty Oak's patents. Nonetheless, Medacta's motion to dismiss asks for an element-by-element analysis of each accused product and demands exacting proof that is not required of Mighty Oak's complaint. That is not the standard by which a motion to dismiss is judged. Under the correct standard, Mighty Oak's complaint passes muster.

1. Under *Disc Disease*, Mighty Oak need only identify the accused products.

Notice pleading under the Federal Rules requires nothing more than a short and plain identification of Mighty Oak's claim to relief, and Mighty Oak has provided that. The Federal Circuit's *Disc Disease* decision squarely implements that requirement, finding that for "simple technology" one need only specifically identify accused products and then alleged that the products "meet each and every element of at least one claim of Plaintiff's patents." *Disc Disease Sol'ns Inc. v. VGH Sol'ns, Inc.*, 888 F.3d 1256, 1260 (Fed. Cir. 2018). Mighty Oak's complaint identifies the accused Medacta products: the MySpine Standard, Low Profile, MC, and S2AI devices. (D.I.

1 ¶ 70.) And Mighty Oak's complaint alleges that each of those products meet each claim of the '678 patent. *Id.* at ¶ 72. Mighty Oak has alleged all that it needs to.

Mighty Oak's allegations are sufficient to place Medacta on notice. Spinal alignment adjuncts are the sort of simple technology contemplated by *Disc Disease*. *See Jackson v. Seaspine Holdings Corp.*, 2022 WL 610703, at *7 (D. Del. Feb. 14, 2022) (citing *Disc Disease* for pleadings of patents that "generally relate to spinal implants and systems used to fixate or align a patient's vertebrae"). And as a spinal alignment adjunct company, Medacta cannot deny that technology in its field is simple technology. *See F2VS Techs., LLC v. Ruckus Wireless, Inc.*, 2018 WL 10048288, at *1 & n.2 (D. Del. July 31, 2018) ("[M]eaningful distinctions" cannot "be made between complaints on . . . the complexity of the technology" when the "relevant audience is the accused infringer"). Mighty Oak's complaint informs Medacta of its allegations with reasonable certainty.

2. Notwithstanding the minimal threshold needed to satisfy *Disc Disease*, Mighty Oak has pled additional facts that more than adequately place Medacta on notice.

Mighty Oak has gone above and beyond the requirements for notice pleading by providing claim charts showing exactly how and where Medacta's products infringe the '678 patent. Medacta's core arguments against this are that (1) Mighty Oak has not provided an element-by-element analysis of the claims of the '678 patent and (2) there is no demonstration *how* the products infringe. Both allegations are incorrect and should be rejected.

As an initial matter, Medacta cannot deny that it does not know what Mighty Oak is accusing of infringement. It answered the four remaining counts of the complaint, demonstrating that Medacta *did* understand which products were accused and of what. And Medacta specifically argues that Count III of the complaint "illustrate[s] the accused 'bridge' being permanently or fixedly [] engaged…." (D.I. 13 at 8.) That allegation belies Medacta's assertions that there is

insufficient notice. To the contrary, it demonstrates that Medacta understood Mighty Oak's complaint; Medacta simply disagrees with its content.

Mighty Oak's complaint confirms that it provides the requisite notice to Medacta of what is accused. It is not the case that element-by-element claiming is required: a "blanket element-by-element pleading standard for patent infringement . . . is unsupported and goes beyond the standard the Supreme Court articulated in *Iqbal* and *Twombly*." *Bot M8 LLC v. Sony Corp. of Am.*, 4 F.4th 1342, 1352 (Fed. Cir. 2021). And even if it were required, Mighty Oak has done exactly that in attaching Exhibit 15, an element-by-element analysis of how Medacta's products infringe claim 11 of the '678 patent.

Medacta persists by asserting that Mighty Oak's claim charts are nonetheless deficient. While *Boston Scientific* and *Swirlate IP* both establish that "fail[ing] to allege facts showing how the accused product performs each step of each claim element"[1] and failing to "connect specific components of the accused systems to elements of the asserted claims"[2] are not enough, that is not what Mighty Oak has done here. Instead, Mighty Oak specifically compiled Medacta's products into a claim chart in Exhibit 15, mapped each product limitation-by-limitation onto the claims of the '678 patent, and annotated each product to identify where each limitation could be found. *See* (D.I. 1 at Ex. 15.) The Court should find Mighty Oak's allegations sufficient.

B. Medacta's motion prematurely seeks summary judgment of noninfringement based upon an erroneous claim construction.

Despite comprehending what Mighty Oak's suit accuses—the sale and offer for sale of Medacta's Accused Products—Medacta seeks to have this Court convert its motion into one for summary judgment of noninfringement. Medacta's assertion that Mighty Oak's complaint cannot

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[1] *Swirlate IP LLC v. Keep Truckin, Inc.*, 2021 WL 3187571, at *2 (D. Del. July 28, 2021).
[2] *Bos. Sci. Corp. v. Nevro Corp.*, 415 F. Supp. 3d 482, 490 (D. Del. 2019).

establish infringement because the complaint "flatly contradicts the plain claim language" amounts to an invitation for the Court to construe the claims. The Court should decline to do so.

1. Claim construction is not permitted at the motion to dismiss stage.

Medacta's request is improper because it argues the merits of its case, not the sufficiency of Mighty Oak's complaint. The "purpose of a motion to dismiss is to *test the sufficiency of the complaint, not to decide the merits*." *Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1350 (Fed. Cir. 2018) (quoting *Gibson v. City of Chi.*, 910 F.2d 1510, 1520 (7th Cir. 1990)) (emphasis in original). Accordingly, claim construction is not appropriate for resolution at the motion to dismiss stage. *Id.* Medacta does not dispute this proposition, but instead seeks to argue that it is not requesting a claim construction. (*See* D.I. 13 at 7.) Medacta's attempt to circumvent the purpose of a motion to dismiss should be rejected.

2. Medacta's motion plainly seeks claim construction.

Despite Medacta's argument to the contrary, the motion plainly seeks claim construction. Infringement analysis requires two steps: first, one examines the intrinsic evidence, including the claim, specification, and prosecution history of the patent, in order to construe the claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc). Only then can one compare the properly construed claims with the accused infringing product. *Markman v. Westview Instrs., Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). That two-step process is exactly what Medacta does in its motion. First, it analyzes the claim language, parsing it and arguing that separate limitations apply to the "arcuate bridge" aspect of claim 11. (*See* D.I. 13 at 10.) Then, Medacta cites the specification as support. (*Id.* at 11-13.) From there, Medacta concludes that the only plausible meaning is that "'[s]electively engaged" requires that the engagement be optional." (*Id.* at 11.) And from that conclusion, Medacta asserts that there is no way its product could infringe. (*Id.* at 12-14.) Those arguments are nothing more than "objections to [Mighty Oak's] theory of

infringement" that "read like classic *Markman* arguments." *Nalco*, 883 F.3d at 1349. That is because what Medacta seeks is a claim construction in furtherance of an improper noninfringement determination. Even if it is true (it is not) that Medacta is only pointing out the "plain language" of the claims, (D.I. 13. at 7, 10), that is nonetheless claim construction. *See Halverson Wood Prods., Inc. v. Classified Sys. LLC*, 2020 WL 5947423, at *3-4 (D. Minn. 2020) ("[A]ssessing the plain meaning of patent terms is claim construction.") The Court should decline to construe the claims at this stage of the proceedings.

3. Medacta's construction is not only premature but incorrectly narrow.

Notwithstanding the impropriety of what Medacta asks, Medacta also proposes an erroneous claim construction. At the motion to dismiss stage, claims are entitled to their "broadest possible construction." *In re Bill of Lading*, 681 F.3d at 1343 n.13. Yet Medacta's proposed construction that "selectively engaged" means that the arcuate bridge of claim 11 of the '678 patent must be removable does not hew to that standard. Illustrating why claim construction at a matter's infancy is a bad idea, Medacta's construction impermissibly restricts the full scope of the invention by ignoring the full disclosure of the entire intrinsic record.

One alternate, possible construction of the phrase "selectively engaged" is that one can select *where* to place the arcuate bridge along the first and second patient-specific elements. The full limitation of claim 11 at issue requires

> an arcuate bridge coupling the first and second patient-specific elements, the arcuate bridge configured to be ***selectively engaged*** with the first and second patient-specific elements at a location beyond the patient's anatomy.

'678 patent cl. 11. Under this reading, "selectively engaged" modifies the later claim limitation "at a location beyond the patient's anatomy," such that "selectively engageable" means that one can choose *where* to place the arcuate bridge relative to the first and second patient-specific

elements, not *whether* to place it. Unlike Medacta's construction, this construction inheres in the intrinsic record's disclosures.

The purpose of the invention is to provide for spinal apparatuses that "may be matched and oriented around the patient's own anatomy." '678 patent at abs. A bridge element allows for that customization and orientation by producing a "desired angle or direction" such that one can "assure that each component of a particular assembly is assembled in the proper location and joined to the proper apparatus." '678 patent at 36: 29-45. That is because "it is often desirable to provide a coupling between retractors located about multiple levels of a patient's spine when performing a MIS procedure." *Id.* at 37:22-25. In that way, "patient-specific data may be used to provide a surgeon with specific settings for adjusting the adjustable coupling element in a desired setting for use in a particular MIS procedure." *Id.* at 37:45-50. One can further see support for this customization in claim 14, a dependent claim depending from claim 11, in which the "arcuate bridge further permits a user to verify proper placement and alignment of the first and second patient-specific elements." *Id.* at claim 14. The arcuate bridge element is thus "selectively engaged" because one selects *where* to engage it, not *whether* to engage it.

Medacta's construction, however, erroneously assumes that "selectively engaged" means that the arcuate bridge of claim 11 must be removable. That is not supported in the intrinsic record. Compare, for example, claim 1 and claim 11. While claim 11 requires a "selectively *engaged*" arcuate bridge, claim 1 requires a "selectively attachable" coupling member. Claim differentiation means that those terms must have different meanings, and indeed, they do. During prosecution, the Applicant added the "selectively engaged" limitation to clarify *where* the arcuate bridge must be located. *See* Declaration of Brandon James Pakkebier Ex. 1 (June 17, 2015 claim amendment).

> 11. (Currently amended) An orthopedic device for use in a minimally invasive surgical procedure, comprising: a first patient-specific element having at least one ~~first~~ patient-specific surface determined from a patient's anatomy and which ~~preoperatively configured to mate and~~anatomically conforms to at least a first subcutaneous anatomic feature~~portion~~ of a specific patient ~~based on medical scans of the patient,~~; a second patient-specific element having at least one second patient-specific surface determined from a patient's anatomy and which ~~preoperatively configured to mate and~~anatomically conforms to at least a second subcutaneous anatomic feature~~portion~~ of a specific patient ~~based on medical scans of the patient~~; and an arcuate bridge coupling the first and second patient-specific elements~~portions~~, the arcuate bridge configured to be selectively engaged with the first and second patient-specific elements at a location beyond the patient's anatomy~~provide clearance above the patient's anatomy between the first and second anatomic portions~~.

Thus, instead of merely "provid[ing] clearance above the patient's anatomy between the first and second anatomic portions," the arcuate bridge of claim 11 must be *located* beyond the patient's anatomy at a selectable location. By contrast, Applicant amended claim 1 in response to prior art to *add* references to joining parts, indicating that Applicants viewed claim 1 as directed to removable coupling members, not the location of components..

Listing of Claims

1. (Currently amended) A surgical device for use in a minimally invasive surgical procedure, comprising:

~~one~~two or more guides each having a proximal and a distal end, the distal ends each comprising ~~a~~ patient-contacting surfaces that anatomically mate with and are determined from~~plurality of distinct and independent patient-contacting surfaces formed to be substantially congruent with a plurality of~~ corresponding subcutaneous anatomical features of a patient;

a coupling member selectively attachable to the proximal ends of a plurality of the two~~one~~ or more guides, thereby forming a medial portion of the surgical device;

wherein the proximal ends of the two or more guides extend outside of the patient and wherein the coupling member is configured to be selectively attached to at least a first guide and a second guide outside of the patient;

wherein the distal ends of the at least a first and second guides of the surgical device are~~is~~ configured to contact the corresponding subcutaneous anatomical features ~~of a patient~~ to ensure proper alignment and placement of the surgical device; and

wherein the ~~one~~two or more guides, when coupled with the coupling member, are oriented in a pre-determined direction.

Id.

As the prosecution history shows, the "selectively attachable" limitation of claim 1 is not the same as the "selectively engaged" limitation of claim 11. That conforms with the plain and ordinary meaning of "selectively": something that is highly specific and can be chosen over existing alternatives. *E.g.*, *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195 (Fed. Cir. 1999). Thus, in the context of claim 11, a "selectively *engageable*" arcuate bridge is one that is specifically chosen to engage *at* a specific point.

It does not matter if Medacta or Mighty Oak's construction is correct, however. At this stage of the proceedings, the Court need not accept either. All that matters is that "the Court might ultimately construe the claims as the patentee proposes" and that "the theory of infringement alleged in the complaint is plausible if such construction (perhaps among others) is adopted." *Wasica Finance GmbH v. Schrader Int'l, Inc.*, 2018 WL 4502178, at *3 (D. Del. Sept. 20, 2018). If those are true, then "the patentee has succeeded in stating a claim on which relief may be

granted." *Id.* And Mighty Oak has done so. If "selectively engaged" means that the arcuate bridge of claim 11 can be placed at a desired location such that the angle of the first and second patient-specific elements can be customized to a patient's anatomy, it does not matter whether a device includes a removable coupling device. It further does not matter, as Medacta asserts, that the device comprises a "unitary constitution." What matters is that the device has been customized such that the arcuate bridge is "selectively engaged" to be unique to a patient's anatomy. And in that respect, Mighty Oak's claim charts make clear that Medacta's products are so customized. That satisfies all that is needed; the Court should reject Medacta's motion.

VI. CONCLUSION

It is not surprising that Medacta believes it has not infringed the '678 patent. But that belief should not be translated into shortcomings in the pleadings. Medacta's motion should be denied as it seeks a premature claim construction. And, because Mighty Oak's complaint establishes its theory of infringement, provides evidence in the form of annotated claim charts supporting that theory, and places Medacta on notice of the accused products and activity, the complaint is sufficient. Medacta's motion should be denied.

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Respectfully Submitted,

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